

**APPENDIX-1**

**EC Ref No.29\_2019 Original Version Date:01.05.2019**

**PARTICIPANT INFORMATION SHEET AND CONSENT FORM**

**Title of the project:** (WE-PPLuS): WEarable technologies for Positive Pregnancy LifestyleS:

**Investigators:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Participant’s Name:**

**MR No**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**1. What should you know?**

You are being invited to take part in a research study. Please speak to a member of the research team if anything you read is not clear or if you would like more information.

**2. What is the study about?**

The overall purpose of the study is to find out if a digital recording of vital bio-signals and benefits of woman’s groups, can facilitate women’s wellbeing, by reducing the incidence and adverse effects of some health conditions, like anaemia and hypertension.

For this part of the study, we aim to collect some vital signs (heart rate, body temperature, blood pressure and oxygen saturation) and see if we can use them to identify specific health conditions. The recording of these bio-signals is totally non-invasive and completely safe for you and your baby. In addition, we would like to know your views about the device.

**3. Why do we need this study?**

The ability to predict pre-eclampsia and anemia using the above-mentioned biomarkers could aid in the management, timely intervention and reduce morbidity and mortality associated with these conditions. We also want to know whether combining this device with the power of women’s group will help impact behavioral change.

**4. What will be done as part of this study?**

At the beginning the researcher will discuss if you have any questions and discuss anything that you would like in relation to this study.

As part of this study we will record the following vital signs using the described means:  
1) We will use a usual electronic blood pressure cuff to measure your Blood Pressure Variability (BPV). We will take one recording at the beginning of the session and one at the end of the session.

2) For the assessment of the Oxygen Saturation Variability (OSV) a pulse oximeter will be placed on your index finger. Your oxygen saturation will be recorded continuously during the assessment session.

3) For the recording of your heart rate, a 3 lead ECG will be used. One electrode will be placed on your right arm, one on your left arm and the third on your left leg. Your heart rate will be recorded continuously during the assessment session.

4) For the recording of your body temperature, an electronic thermometer will be used. We will take one recording at the beginning of the session and one at the end of the session.

In addition, based on your clinical record, a member of the clinical group will inform us about your health status. Only details on if you are healthy, or having raised blood pressure also called hypertension, anaemia ( low iron) or infection will be shared. You will also be asked about your age and how many weeks you are pregnant.

**The duration of the assessment session is 5 minutes.**

Once the blood pressure cuff will be placed on your arm, the oximeter on your finger and the ECG as described above, the researcher will start recording (0 minutes). At that point, your temperature will be recorded as well. The recordings will be stopped after 5 minutes when a last temperature measurement will be made. The overall duration is 5 minutes, during which you will have to remain seated. Once the recording session will be completed, all the sensors will be removed.

After this, we will ask your views by completing a short questionnaire, which has in total 6 questions. The maximum estimated time for the completion of the survey is 5 minutes.

**Time commitment: The maximum time commitment including any discussion with the participant and preparation is 30 minutes.**

**5. Are there any risks?**

There are no benefits or risks for you in this study, but the information we get from it will help to increase the understanding of the potential use of this integrated system in maternity care. If your blood pressure, body temperature and/or oxygen saturation look unusual we will inform a clinician who will take care of you.

**6. Will my data be safe?**

All data will be saved with a serial number, and no personal identifiers will be used. There will be no way to link your name or identifying personal details to your data. The data will be stored for 25 years, at the University of Central Lancashire’s secured network. Biometric data will not be shared and there is no clinical intervention involved.

**7. Are there any costs involved?**

There are no costs involved in this study.

**8. Can I refuse to participate? Will refusal affect my clinical care?(** Do you have to take part?)

No, taking part is voluntary and it is up to you to decide. If you don’t want to take part, you do not have to give a reason and no pressure will be put on you to try and change your mind. If you choose not to take part, or to pull out during the procedure this will not affect you and/or your standard care in any way.

**9. Can I withdraw from the study after enrollment? Will withdrawal affect my clinical care or my clinical condition?**

You are free to withdraw from the study at any time before the vital signs recording is complete, without giving a reason. As the information we collect will not be linked with your name or any identifying details, we will not be able to withdraw your information after the measurement session is complete.

**10. Whom can I contact if I need any further clarification or in case of an emergency?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you subsequently feel distressed or remain unhappy and wish to complain formally, you can do this through contacting Katherine Stringer-Mob No. 703266448

If you need any further information or in case of emergency please contact us on:

Katherine Stringer-Mob No. 703266448

After having read the above information provided, I am enrolling in the study and I am willing to provide the information needed and undergo the processes as outlined.

Name of the Patient: Signature of the Patient

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the Principal Investigator Signature of the Principal Investigator

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_